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U.S. Department of Labor

Assistant Secretary for
Occupational Safety and Health
Washington, D.C. 20210



OSHA Instruction CPL 2-2.44A

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SUBJECT: Enforcement Procedures for Occupational Exposure
to Hepatitis B Virus (HBV) and Human Immuno-
deficiency Virus (HIV).

- A. Purpose. This instruction provides uniform inspection procedures and guidelines to be followed when conducting inspections and issuing citations under section 5(a)(1) of the Act and pertinent standards for health care workers potentially exposed to HBV and HIV.
- B. Scope. This instruction applies OSHA-wide.
- C. Cancellation. This instruction cancels OSHA instruction CPL 2-2.44, January 19, 1988.
- D. References.
1. OSHA Instruction CPL 2.45A, April 18, 1983, the Field Operations Manual (FOM).
 2. OSHA Instruction ADM 1-1.12A, April 1, 1984, the Integrated Management Information System (IMIS) Forms Manual.
 3. OSHA Instruction CPL 2-2.36, November 30, 1983, Hepatitis B Risks in the Health Care System.
 4. Centers for Disease Control. Acquired Immuno-deficiency Syndrome, AIDS--Recommendations and Guidelines November 1982-November 1986.
 5. Centers for Disease Control Morbidity and Mortality Weekly Report. Update on Hepatitis B Prevention. June 19, 1987; Vol. 36, No.23.
 6. Centers for Disease Control Morbidity and Mortality Weekly Report. 1988 Agent Summary Statement for Human Immunodeficiency Virus and Report on Laboratory-Acquired Infection with Human Immunodeficiency Virus. April 1, 1988; Vol. 37, No. S-4.

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- E. Action. Regional Administrators and Area Directors shall ensure that the policies and procedures explained in this instruction are implemented in scheduling and conducting inspections. Regional Administrators shall further ensure that all relevant procedures established in this instruction are adhered to by State 7(c)(1) consultation projects.
- F. Federal Program Change. This instruction describes a Federal Program change which affects State programs. Each Regional Administrator shall:
1. Ensure that this change is promptly forwarded to each State designee.
 2. Explain the technical content of this change to the State designee as requested.
 3. Ensure that State designees are asked to acknowledge receipt of this Federal program change in writing, within 30 days of notification, to the Regional Administrator. This acknowledgment must include the State's intention to follow the appropriate procedures in this instruction, or a description of the State's alternative procedures which are "at least as effective" as the Federal guidelines. Any alternative State policies must be submitted as a plan supplement within 6 months.
 - a. If a State intends to follow the inspection procedures described in this instruction, the State must submit either a revised version of this instruction, adapted as appropriate to reference State law, regulations and administrative structure, or a cover sheet describing how references in this instruction correspond to the State's structure. The State's acknowledgment letters may fulfill the plan supplement requirement if the appropriate documentation is provided.
 - b. If the State adopts an alternative to Federal enforcement policies, the State's submission must identify and provide a rationale for all substantial differences from Federal policies in order for OSHA to judge whether a different State procedure is as effective as comparable Federal policy.

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- c. Although States are not required to enforce General Duty provisions, they are strongly urged to do so.
4. Advise State designees of the following:
- a. In order to ensure a sound and consistent national enforcement and litigation strategy in relation to the complex issues addressed by this instruction, State implementation of the procedures in this instruction, or comparable State procedures, must be carefully coordinated with OSHA.
 - b. The State is also responsible for extending coverage under its procedures for addressing occupational exposure to HBV and HIV in the public sector, such as police, fire, ambulance and other emergency response workers.
 - c. The Directorate of Technical Support is available to assist the States in locating expert witnesses. (See paragraph O., Expert Witnesses.)
 - d. In regard to paragraph I., Inspection Scheduling, Goal and Scope, the State's response to the Regional Administrator is to include a projection of the number of inspections the State expects to conduct in both the private and public sector.
5. After Regional review of the State plan supplement and resolution of any comments thereon, forward the State submission to the National Office in accordance with established procedures. The Regional Administrator shall provide a judgment on the relative effectiveness of each substantial difference in the State plan change and an overall assessment thereon with a recommendation for approval or disapproval by the Assistant Secretary.
6. Review policies, instructions and guidelines issued by the State to determine that this change has been communicated to State program personnel.

G. Definitions.

1. Health Care Facility. Those establishments listed under the Standard Industrial Classification (SIC) codes 80** and 7261; and clinics, health units, and nurses' stations at industrial work sites.
2. Health Care Worker. An employee of a health care facility including, but not limited to, nurses, physicians, dentists and other dental workers, optometrists, podiatrists, chiropractors, laboratory and blood bank technologists and technicians, research laboratory scientists, phlebotomists, dialysis personnel, paramedics, emergency medical technicians, medical examiners, morticians, housekeepers, laundry workers and others whose work may involve direct contact with body fluids, as defined below, from living individuals or corpses.
3. Universal Precautions. The term "universal precautions" refers to a system of infectious disease control which assumes that every direct contact with body fluids is infectious and requires every employee exposed to direct contact with body fluids to be protected as though such body fluids were HBV or HIV infected. Therefore, universal precautions are intended to prevent health care workers from parenteral, mucous membrane, and nonintact skin exposures to blood-borne pathogens.
4. Body Fluids. Fluids that have been recognized by CDC as directly linked to the transmission of HIV and/or HBV and/or to which universal precautions apply: blood, semen, blood products, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, and concentrated HIV or HBV viruses.
5. Phlebotomist. A phlebotomist is any health care worker who draws blood samples.
6. Infectious Control (IC) Program. An IC program is the establishment's oral or written policy and implementation of procedures relating to the control of infectious disease hazards where employees may be exposed to direct contact with

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body fluids. An IC Program must address all of the areas outlined in this directive.

7. Joint Advisory Notice. Department of Labor/Department of Health and Human Services-Joint Advisory Notice (Federal Register, Vol. 52, No. 210; October 30, 1987) is a list of recommendations developed to assist employers in implementing the Centers for Disease Control (CDC) guidelines.
- H. Background. In September 1986, OSHA was petitioned by various unions representing health care employees to develop a standard to protect workers from occupational exposure to blood-borne diseases. Although the Agency has decided to pursue development of such a standard, as a result of recent rulemaking petitions and OSHA's evaluation of those petitions, the Agency has concluded that the risk of contracting hepatitis B and AIDS among members of various occupations within the health care system requires an immediate response through a variety of existing mechanisms.
 1. Occupational exposure may occur in many ways, including needlestick and cut injuries. Health care workers employed in certain occupations are assumed to be at high risk for blood-borne infections due to their routinely increased exposure to body fluids from potentially infected patients. These high risk occupations include but are not limited to physicians, pathologists, dentists and dental technicians, x-ray technicians, phlebotomists, emergency room, intensive care and operating room nurses and technicians, laboratory and blood bank technologists and technicians. Other health care workers who may be directly exposed to such body fluids depending on their exact work assignments include such occupations as housekeeping personnel, laundry workers, orderlies, morticians, research laboratory workers, paramedics, medical examiners. Employees in any occupation where they are directly exposed to body fluids are considered to be at substantial risk of occupational exposure to HIV and/or HBV.
 2. Ward clerks and administrators have virtually no increased risk of contact with body fluids as a result of their employment; they are thus at no

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greater risk of contracting blood-borne diseases than other members of the general population.

3. Neither HBV nor HIV is transmitted by casual contact in the workplace.
4. The employer's obligations are those set forth in the Occupational Safety and Health Act (OSH Act) of 1970. However, the CDC has published guidelines to protect workers from HBV and HIV (See Appendices A & B). OSHA is relying on these guidelines as reflecting an appropriate and widely recognized and accepted standard of protection to be followed by health care employers in carrying out their responsibilities under the OSH Act.
5. The same personal protective equipment and work practices used to prevent occupational transmission of HBV are effective in preventing occupational transmission of HIV. The CDC has called for use of "universal precautions" when working with blood and/or body fluids from any patient.
6. One difference between the two viruses is that there is currently a vaccine to prevent HBV infection, which the CDC has recommended for persons at substantial risk of occupational exposure, but there is no vaccine for HIV.

I. Inspection Scheduling, Goal and Scope.

1. Inspection scheduling shall be conducted in accordance with the procedures outlined in the FOM, Chapter II, and for Federal agencies, Chapter XIII, except as modified in the following sections.
2. The National Office shall develop and distribute a list of health care establishments by State to the appropriate Regional Administrators to identify the establishments to be programmed for inspection within the Region.
 - a. This list shall be randomly selected from among all establishments identified as being within the health care industries, viz., those industries having primary Standard Industrial Classification (SIC) codes 80** (Health Ser-

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vices) and 7261 (Funeral Service and Crematories).

- b. A widely available commercial listing shall be the source of such establishments (Duns Marketing Service).
 - c. All establishments listed as having less than 11 employees shall be excluded from the list.
 - d. More establishments will be provided to the Regions than will actually be needed to allow for replacement of establishments.
3. The Regional Administrator shall use an additional random selection method to identify the establishments actually to be programmed for inspection within the Region.
- a. The number of health care establishments to be selected from the list provided by the National Office shall be at least equal to the inspection goal identified in the annual program plan developed for the Region.
 - b. The names of the establishments selected by the Regional Administrator shall be distributed to the appropriate Area Office and shall constitute the Inspection Register for that office.
 - c. An inspection of all establishments listed on the Inspection Register shall be conducted unless they are deleted for some legitimate reason.
4. Any establishment deleted shall be replaced by another establishment selected according to I.3.
- a. Area Directors shall inform the Regional Administrator of any deletions.
 - b. The Regional Administrator shall select the next establishment by random number procedure from the list provided by the National Office.
 - c. Because of the random number selection procedures, it may happen that the next establishment does not belong to the same

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Area Office jurisdiction and may have to be assigned to an Area Office other than the one deleting the first establishment.

5. When an inspection of an establishment listed on the Health Care Inspection Register is not conducted because the employer has refused entry, a warrant shall be sought in accordance with the current procedure for handling such refusals. Only if the court refuses to grant a warrant or if the Regional Solicitor declines to apply for a warrant, is such an establishment to be replaced according to I.3.
6. Each Region shall conduct the minimum number of health care facility inspections (e.g., hospitals, clinical laboratories, blood donor centers, etc.) annually identified in its program plan.
7. All inspections, programmed or unprogrammed, conducted at health care facilities or at other facilities (such as manufacturing plants) which support an onsite health care unit shall be directed to all areas involving the hazard of direct exposure to body fluids potentially contaminated with HBV or HIV.
 - a. Primary areas of concern are emergency rooms, operating rooms, direct patient care areas, laboratories, and x-ray. Secondary areas of concern are laundry and housekeeping.
 - b. Records review procedures for the purpose of conducting a records only inspection do not apply.
 - c. Expansion to additional units may be appropriate when:
 - (1) The IC program shows significant deficiencies in complying with OSHA requirements, as set forth in this instruction, that may indicate the existence of more widespread problems.
 - (2) Relevant complaints are received from employees which are specifically related to direct exposures to body fluids.

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J. Inspection Procedures. The procedures given in the FOM, Chapter III, shall be followed except as modified in the following sections.

1. When entering a hospital or health care facility, the CSHO shall locate the Hospital Administrator, the Medical Director or other person in charge and present credentials.
2. Health care facilities generally administer internal IC programs. This function may be performed by a committee or an individual. Upon entry the CSHO shall request the presence of the infection control nurses and/or other individuals who will be responsible for providing records pertinent to the inspection.
3. Careful examination of the facility's IC program is the core element of these inspections. Occupational injury and illness records shall be carefully scrutinized, and employees selected from all appropriate areas of the facility shall be interviewed to verify both the accuracy of the OSHA-200 records and the effectiveness of the IC program.

NOTE: Employers are not required normally to record needlesticks on the OSHA 200. However, if such needlesticks require medical treatment (i.e., gamma globulin) and are identified as causes of diagnosed occupationally related AIDS, AIDS Related Complex, or hepatitis B they shall be recorded.

4. In the event the facility being inspected does not have a formal IC program, employee interviews, combined with an inspection of appropriate areas of the facility shall be used to determine the effectiveness of the establishment's efforts to protect employees from exposure to potential infectious disease sources.
5. CSHOs shall use appropriate caution when entering patient care areas of the facility. When such visits are judged necessary for determining actual conditions in the facility, the privacy of patients shall be respected. Photographs of patients will not normally be necessary and in no event shall

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identifiable photographs be taken without their consent.

6. The walkaround portion of the inspection shall consist of a spot-check approach. The CSHO shall identify on the basis of professional judgment what areas should be physically checked out and to what extent. It is not expected that a comprehensive walkaround inspection of the workplace will be necessary. The CSHO is to be satisfied that an IC program is in place and judged to be effective.
7. If an inspection is conducted in an establishment outside of SIC codes 80** and 7261, and a health care unit is on site, the provisions of Sections J through T apply and shall be enforced.

K. Federal Agency Facilities. Health care facilities owned by agencies of the Federal Government are subject to inspection under this instruction.

1. Where an inspection other than one scheduled on the regular Federal establishment targeting list is to be made at a Federal health care facility in accordance with this instruction, notification of agency headquarters personnel, through the Office of Federal Agency Programs (OFAP), shall be accomplished prior to any facility visits.
2. Actual onsite visits shall be coordinated between Regional/Area Office and the establishment being inspected.

L. Citation Policy. The provisions of the FOM, Chapters IV and V, shall be followed when issuing citations for hazards related to blood-borne infectious diseases.

1. The following requirements apply when citing hazards found in health care facilities. Employers must comply with the provisions of these requirements whenever an employee may reasonably be expected to have direct contact with body fluids regardless of whether the patient is known to have been infected with HBV or HIV. This policy is based on the widespread nature of these viruses and the consequent risk to the health care workers described above. It is also based on the need to maintain patient confidentiality and HBV and HIV

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testing limitations.

- o 29 CFR 1910.132--Personal protective equipment.
 - o 29 CFR 1910.22(a)(1) and (a)(2)--General requirements, Housekeeping.
 - o 29 CFR 1910.141(a)(4)(i) and (ii)--Sanitation, Waste disposal.
 - o 29 CFR 1910.145(f)--Specifications for accident prevention signs and tags.
 - o Section 5(a)(1)--General Duty Clause and Executive Order 12196, Section 1-201(a) for Federal facilities.
2. Whenever a hazardous condition exists that is not covered by one of the standards listed above, and the decision is made not to cite the condition under the general duty clause, the appropriate letter shall be sent advising the employer of the hazardous conditions and suggesting corrective action.
3. Such recommendations made to employers shall be noted in the case file for special attention in subsequent inspections.
4. Multi-Employer Work Site. The following citation guidelines apply in multi-employer worksites.
- (a) Health care facilities shall be cited for standards and section 5(a)(1) violations to which their own employees are exposed.
 - (b) They shall also be cited for standards (but not 5(a)(1)) violations to which employees of other employers on their premises are exposed to the extent that they control the hazard. For example, they shall be cited for not providing personal protective equipment to unprotected employees of other employers on their premises.
 - (c) Physicians who are members of professional corporations are generally considered to be employees of that corporation. Therefore, the

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corporation may be cited for all violations affecting those physicians. Hospitals where they work may also be cited for standards violations (but not 5(a)(1)) to which they are exposed.

- (d) No citation shall be issued where the only persons exposed are physicians who are sole practitioners or partners, and thus not employees under the Occupational Safety and Health Act.

M. Violations. The IC program shall be carefully evaluated to determine compliance with OSHA requirements, as clarified by those CDC guidelines relating to health care worker safety and health. The description of the OSHA requirements in this section is based upon those guidelines. Violations of OSHA requirements will normally be classified as serious.

1. 29 CFR 1910.132(a) and (c). The standard provides in pertinent part:

"(a) Application. Protective equipment, including personal protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, shall be provided, used, and maintained in a sanitary and reliable condition wherever it is necessary by reason of hazards of processes or environment, ... encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation or physical contact.

(c) Design. All personal protective equipment shall be of safe design and construction for work to be performed."

The following personal protective measures shall have been addressed by the IC program and verified by interviews and walkaround.

- a. Gloves. The use of gloves will vary according to the procedure involved. The use of disposable gloves is indicated for procedures where body fluids are handled.

- (1) The use of gloves is particularly important in the following circumstances:
 - a If the health care worker has cuts, abraded skin, chapped hands, dermatitis or the like.
 - b During instrumental examination of oropharynx, gastrointestinal tract and genitourinary tract.
 - c When examining abraded or non-intact skin or patients with active bleeding.
 - d During invasive procedures.
 - e During all cleaning of body fluids and decontaminating procedures.
 - (2) Gloves must be of appropriate material, usually intact latex or intact vinyl, of appropriate quality for the procedures performed, and of appropriate size for each health care worker. Where gloves do not meet these requirements 29 CFR 1910.132(c) shall be cited.
 - (3) Employers shall not wash or disinfect surgical or examination gloves for reuse.
 - (4) General purpose utility (rubber) gloves worn by maintenance, housekeeping, laundry or other non medical personnel may be decontaminated and reused.
 - (5) No gloves shall be used if they are peeling, cracked, or discolored, or if they have punctures, tears, or other evidence of deterioration. Failure to meet these requirements shall be cited under 29 CFR 1910.132(c).
- b. Gowns. The use of gowns, aprons, or lab coats is required when splashes to skin or clothing with body fluids are likely to occur. Gowns, including surgical gowns, shall be made of or lined with impervious material and shall

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protect all areas of exposed skin.

- c. Masks and Eye Protectors. The use of masks and protective eyewear or face shields is required when contamination of mucosal membranes (eyes, mouth or nose) with body fluids such as splashes or aerosolization of such material (e.g., during surgical or dental procedures), is likely to occur. They are not required for routine care.
- d. Resuscitation Equipment. Pocket masks, resuscitation bags, or other ventilation devices shall be provided in strategic locations as well as to key personnel (e.g. paramedics) where the need for resuscitation is likely. This will minimize the need for emergency mouth-to-mouth resuscitation.
- e. Invasive Procedures. Personal protective equipment as described above shall be used when performing invasive procedures to avoid exposure. When a health care worker's skin or mucous membranes may come in contact with body fluids, gowns, masks, and eye protection shall be worn, as noted above.
- f. Phlebotomy. Gloves shall generally be provided to and used by phlebotomists. Employers who do not make them available shall be cited for failure to provide under 29 CFR 1910.132(a). Employers who make gloves available, but discourage or prohibit their use shall be cited for failure to use under 29 CFR 1910.132(a), if in fact the gloves are not being used. However, no citation for failure to use shall be issued where the phlebotomist voluntarily and without the encouragement of the employer does not wear gloves, unless the following circumstances exist:
 - (1) For performing phlebotomy when the health care worker has cuts, scratches, or other breaks in his/her skin.
 - (2) In situations where the CSHO and/or health care worker judges that hand contamination with blood may occur, for example, when

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performing phlebotomy on an uncooperative patient.

(3) For performing finger and/or heel sticks in infants and children.

(4) When persons are receiving training in phlebotomy.

- g. Dentistry. Gloves are required for contact with oral mucous membranes. Surgical mask and protective eyewear or chin-length plastic face shields are required during dental procedures in which splashing, spattering or aerosolization of blood, saliva or gingival fluids is likely. (Saliva and gingival fluids are included because of the likelihood that they contain blood in their setting.)
- h. Laboratories. The use of gloves are required for processing body fluid specimens. Masks and protective eyewear are required when the worker's mucosal membranes may come in contact with body fluids.
- i. Postmortem Procedures. Persons performing or assisting in postmortem procedures are required to wear personal protective equipment as noted above to avoid exposure to body fluids.

2. 29 CFR 1910.22(a)(1) and (a)(2). The standard provides in pertinent part:

"(a) Housekeeping. (1) All places of employment, passageways, storerooms, and service rooms shall be kept clean and orderly and in a sanitary condition.

(2) The floor of every workroom shall be maintained in a clean and, so far as possible, a dry condition...."

The IC program shall have identified housekeeping operations involving substantial risk of direct exposure to body fluids and shall have addressed the proper precautions to be taken while cleaning

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rooms and blood spills. The application of these procedures shall be verified by employee interviews and the walkaround.

- a. Room Cleaning Where Body Fluids are Present. Schedules shall be as frequent as necessary according to the area of the institution, type of surface to be cleaned, and the amount and type of soil present.
 - b. Disinfectants. Chemical germicides that are approved for use as hospital disinfectants and are tuberculocidal when used at recommended dilutions shall be used to decontaminate spills of blood and other body fluids. A solution of 5.25 percent sodium hypochlorite (household bleach) diluted between 1:10 and 1:100 with water or other suitable disinfectant shall be used for disinfection following the initial cleanup.
3. 29 CFR 1910.141(a)(4)(i) and (ii). The standard provides in pertinent part:
- "(4) Waste disposal. (i) Any receptacle used for putrescible solid or liquid waste or refuse shall be so constructed that it does not leak and may be thoroughly cleaned and maintained in a sanitary condition. Such a receptacle shall be equipped with a solid, tight-fitting cover, unless it can be maintained in a sanitary condition without a cover. This requirement does not prohibit the use of receptacles which are designed to permit the maintenance of a sanitary condition without regard to the aforementioned requirements.
- (ii) All sweepings, solid or liquid wastes, refuse, and garbage shall be removed in such a manner as to avoid creating a menace to health and as often as necessary or appropriate to maintain the place of employment in a sanitary condition."

The IC program shall have addressed the handling and disposal of the following potentially contaminated items. The effectiveness of the program in this regard shall be verified through employee

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interviews and the walkaround.

a. Sharp instruments and disposable items.

Needles shall not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand.

(1) After they are used, disposable syringes and needles, scalpel blades, and other sharp items shall be placed in puncture-resistant containers for disposal.

(2) Such containers shall be easily accessible to personnel needing them and located in all areas where needles are commonly used, including emergency rooms, intensive care units, and surgical suites and shall be so constructed that they will not spill their contents if knocked over and will not themselves allow injuries when handled.

(3) These containers shall also be located on patient floors and any other setting where blood is drawn and needles are used.

b. Lab specimens. All specimens of body fluids shall be put in a well constructed container with a secure lid to prevent leaking during transport and shall be disposed of in an approved manner. Contaminated materials used in laboratory tests should be decontaminated before reprocessing or be placed in bags and disposed of in accordance with institutional policies for disposal of infectious waste.

4. 29 CFR 1910.145(f). The standard provides in pertinent part:

"(f)(3) Use. Tags shall be used as means to prevent accidental injury or illness to employees who are exposed to hazardous or potentially hazardous conditions, equipment or operations which are out of the ordinary, unexpected or not readily apparent. Tags shall be used until such time as the identified hazard is eliminated or the hazardous operation is completed. Tags need not be used where signs, guarding or other positive

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means of protection are being used.

(4) General tag criteria. All required tags shall meet the following criteria:

(i) Tags shall contain a signal word and a major message.

(a) The signal word shall be ... "BIOHAZARD," or the biological hazard symbol.

(b) The major message shall indicate the specific hazardous condition or the instruction to be communicated to the employee.

(ii) The signal word shall be readable at a minimum distance of five feet (1.52m) or such greater distance as warranted by the hazard.

(iii) The tag's major message shall be presented in either pictographs, written text or both.

(iv) The signal word and the major message shall be understandable to all employees who may be exposed to the identified hazard.

(v) All employees shall be informed as to the meaning of the various tags used throughout the workplace and what special precautions are necessary.

(vi) Tags shall be affixed as close as safely possible to their respective hazards by a positive means such as string, wire, or adhesive that prevents their loss or unintentional removal.

(f)(8) Biological hazard tags. (i) Biological hazard tags shall be used to identify the actual or potential presence of a biological hazard and to identify equipment, containers, rooms, experimental animals, or combinations thereof, that contain or are contaminated with hazardous biological agents."

The IC program shall have addressed the labeling procedures to be followed in the facility. That these procedures are followed shall be confirmed by employee interviews and the walkaround.

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- a. Bags or other receptacles containing articles contaminated with potentially infectious material, including contaminated disposable items, must be tagged or otherwise identified. The tag shall have the signal word "BIOHAZARD" or the biological hazard symbol. The tag shall indicate that the bag could contain infectious wastes and give any additional instructions; e.g., if the outside of the bag is contaminated with body fluids, a second outer bag should be used.
- b. If tags are not used, other equally effective means of identification shall be used (e.g., red bagging).
- c. Employees shall be informed of the meaning of tags. With respect to tagged material, they shall also be instructed to use double bagging where puncture or outside contamination is likely.

5. Section 5(a)(1). Section 5(a)(1) provides:

"Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;"

- a. Section 5(a)(1) citations must meet the requirements outlined in the FOM, Chapter IV, and can be issued only where there is a hazard which cannot be abated by implementing an abatement method required by the standards above. All applicable abatement methods identified as correcting the same hazard shall be issued under a single 5(a)(1) citation.
- b. If a citation under 5(a)(1) is justified, the citation, after setting forth the SAVE for section 5(a)(1), shall state:

Health care workers (specify categories, such as doctors, nurses, etc.) (Specify location) were exposed to the hazard of being infected by HBV and/or HIV through

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possible direct contact with blood or other body fluids. Feasible and useful abatement methods for reducing this hazard, among others, are: (List abatement methods not required by the standards which employer is not implementing.)

- c. Recognition for purposes of citing section 5(a)(1) is recognition of the hazard of being infected with HBV and/or HIV through possible direct contact with body fluids. The health care industry generally accepts and, therefore, recognizes the determination of this hazard by the CDC, which is the acknowledged authority in this area. The employer's IC program can also constitute evidence of recognition.
- d. The following are examples of feasible and useful abatement methods. The non-use of any of these methods is likely to result in the continued existence of a serious hazard and, may, therefore, allow citation under 5(a)(1). Consequently, all of these methods shall have been implemented. To determine whether they are being implemented, the CSHO shall evaluate the IC program and verify with employee interviews and the walkaround.
 - (1) Hepatitis B Vaccination. The facility's IC policy regarding hepatitis B vaccinations shall address all circumstances warranting such vaccinations and shall identify employees at substantial risk of directly contacting body fluids. All such employees shall be offered hepatitis B vaccinations in amounts and at times prescribed by standard medical practice.
 - (2) Linen. The IC program shall have identified all laundry operations involving substantial risk of direct exposure to body fluids. Linen soiled with body fluids shall be handled as little as possible and with minimum agitation to prevent contamination of the person handling the linen. All soiled linen shall be bagged at the location where it was used; it shall not be sorted

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or rinsed in patient-care areas. Soiled linen shall be placed and transported in bags that prevent leakage.

- (3) Reusable Equipment. Standard sterilization and disinfection procedures currently recommended for hepatitis B in a variety of health care settings are adequate to sterilize or disinfect instruments, devices, or other items contaminated with body fluids. A recommended source of information is the CDC's Guidelines for Hospital Environmental Control: Cleaning, Disinfection and Sterilization of Hospital Equipment.
- (4) Bagging of Articles. Objects that are contaminated with potentially infectious materials shall be placed in an impervious bag. If outside contamination of the bag is likely, a second bag shall be added.
- (5) Handwashing. After removing gloves, hands or other skin surfaces shall be washed thoroughly and immediately after contact with body fluids.
- (6) Follow-up Procedures After Possible Exposure to HIV/HBV:
 - (a) If a health care worker has a percutaneous (needlestick or cut) or mucous membrane (splash to eye, nasal mucosa, or mouth) exposure to body fluids or has a cutaneous exposure to blood when the worker's skin is chapped, abraded, or otherwise nonintact, the source patient shall be informed of the incident and tested for HIV and HBV infections, after consent is obtained.
 - (b) If patient consent is refused or if the source patient tests positive, the health care worker shall be evaluated clinically and by HIV antibody testing as soon as possible and advised to report and seek medical

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evaluation of any acute febrile illness that occurs within 12 weeks after exposure. HIV seronegative workers shall be retested 6 weeks post-exposure and on a periodic basis thereafter (12 weeks and 6 months after exposure).

- (c) Follow up procedures shall be taken for health care workers exposed or potentially exposed to HBV. The types of procedures depends on the immunization status of the worker (i.e., whether HBV vaccination has been received and antibody response is adequate) and the HBV serologic status of the source patient. The CDC Immunization Practices Advisory Committee has published its recommendations regarding HBV postexposure prophylaxis in table format in the June 7, 1985, Morbidity and Mortality Weekly Report.
 - (d) If an employee refuses to submit to the procedures in (b) or (c) above when such procedures are medically indicated, no adverse action can be taken on that ground alone since the procedures are designed for the benefit of the exposed employee.
- (7) Training and Education of Health Care Workers. The employer's training program shall be evaluated in accordance with Appendix C.
- (a) All high risk health care workers such as those listed in H.1. shall receive education on precautionary measures, epidemiology, modes of transmission and prevention of HIV/HBV. Health care workers shall be counseled regarding possible risks to the fetus from HIV/HBV and other associated infectious agents.

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- (b) In addition, such high risk workers must receive training regarding the location and proper use of personal protective equipment. They shall be trained concerning proper work practices and, if the facility has implemented them, shall understand the concept of "universal precautions" as it applies to their work practices. They shall be trained about the meaning of color coding or other methods (except tags) used to designate contaminated articles or infectious waste. Where tags are used, training about tags and precautions to be used in handling contaminated articles or infectious waste is governed by 29 CFR 1910.145(f). (See section M.4.) Workers shall receive training about procedures to be used if they are exposed to needlestick or to body fluids.

N. Other Standards.

1. The hazard communication standard, 29 CFR 1910.1200 only applies to hazardous chemicals or physical hazards in the workplace and thus does not apply to biological hazards such as blood borne diseases.
2. A record concerning employee exposure to HIV and/or HBV is an employee exposure record within the meaning of 29 CFR 1910.20. A record about HIV and/or HBV status is also an employee medical record within the meaning of 29 CFR 1910.20. However, under 29 CFR 1913.10, the CSHO may obtain these records for purposes of determining compliance with 29 CFR 1910.20.
3. Generally, 29 CFR 1910.134 does not apply since there are no respirators approved for biohazards. However, placing respirators in areas where they could be contaminated by body fluids constitutes a violation of 29 CFR 1910.134(b)(6).

- O. Expert Witnesses. The Directorate of Technical Support will assist the Regional Offices and the States in

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locating expert witnesses.

1. In the event that a 5(a)(1) citation is contested, proper expert witness support shall be immediately obtained. Issues which the expert must be prepared to address include:
 - a. The risk to workers associated with the exposure circumstances.
 - b. Existence, feasibility and utility of abatement measures.
 - c. Recognition of the hazard in the industry, by the employer.
2. Expert witnesses may also be necessary in other cases, particularly those involving 29 CFR 1910.132(a).

P. Recording in the IMIS. Current instructions for completing the appropriate inspection classification boxes (Items 24 and 25) on the OSHA-1, Inspection Report, as found in the IMIS Manual shall be applied when recording inspections conducted at health care facilities or at facilities with health care units:

1. Inspections conducted in such facilities shall be coded as "Comprehensive" or "Partial" in Item 35 of the OSHA-1, as appropriate. Such inspections shall not be coded as records only inspections.
2. The OSHA-1 for health care facility or unit inspections scheduled as a result of a complaint shall be marked as "Safety" or "Health" as appropriate (Item 21.), "Complaint" (Item 24.), and "National Emphasis Program" (Item 25d.). Record "BLOOD" in the space in Item 25d.
3. The OSHA-1 for health care facility or unit inspections scheduled from the Safety or the Health Establishment List or from the Health Care Establishment List shall be marked as "Safety" or "Health," as appropriate (Item 21.), "Planned" (Item 24h.), "Safety" or "Health Planning Guide" as appropriate (Item 25b.), "National Emphasis Program" (Item 25d.). Record "BLOOD" in the space in Item 25d.

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4. The OSHA-1 for any unprogrammed safety or health inspection conducted in a health care facility or unit shall be marked "Unprogrammed" (Item 24a. through g., as appropriate), "National Emphasis Program" (Item 25d.) and "BLOOD" recorded in the space in Item 25d.

Q. Referrals.

1. When a complaint or inquiry is received from a source in a State plan State regarding occupational exposure to blood-borne disease, the Regional Administrator shall refer it to the State plan designee for action.
2. When a complaint or inquiry regarding occupational exposure to blood-borne disease in a State or local government health care facility is received in a State without an OSHA approved State plan, the Regional Administrator shall refer it to the appropriate State public health agency or local health agency with jurisdiction over the health care facilities.

R. Personal Protective Equipment for CSHOs.

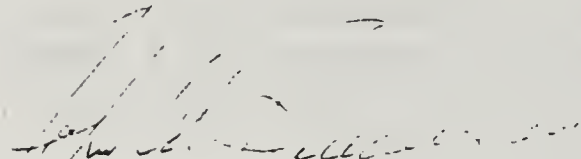
1. CSHOs shall not participate in activities that will require them to come into contact with body fluids, needles or other sharp instruments contaminated with blood. To evaluate such activities, CSHOs normally shall establish the existence of hazards and adequacy of work practices through employee interviews and shall observe them at a safe distance.
2. CSHOs shall take necessary precautions to avoid direct contact with body fluids. It will not normally be necessary for CSHOs actually to enter hazardous areas and, therefore, to use personal protective equipment. On the rare occasions when entry into potentially hazardous areas is judged necessary, the CSHO shall be properly equipped as required by the health care facility as well as by his/her own professional judgement, after consultation with the supervisor (FOM, Chapter III).

S. Copies of Citations. Copies of all citations issued pursuant to this program shall be sent expeditiously to

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the Office of Health Compliance Assistance through the Director of Field Programs. Such information is necessary for program monitoring and evaluation.

- T. Informal Settlement Agreements and Notices of Contest.
Copies of all settlement agreements and notices of contest shall be sent expeditiously to the Office of Health Compliance Assistance through the Director of Field Programs.



John A. Pendergrass
Assistant Secretary

DISTRIBUTION: National, Regional and Area Offices
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APPENDIX A

CENTERS FOR DISEASE CONTROL

June 24, 1988 / Vol. 37 / No. 24



377 Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings

MORBIDITY AND MORTALITY WEEKLY REPORT

Perspectives in Disease Prevention and Health Promotion

Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings

Introduction

The purpose of this report is to clarify and supplement the CDC publication entitled "Recommendations for Prevention of HIV Transmission in Health-Care Settings" (1).*

In 1983, CDC published a document entitled "Guideline for Isolation Precautions in Hospitals" (2) that contained a section entitled "Blood and Body Fluid Precautions." The recommendations in this section called for blood and body fluid precautions when a patient was known or suspected to be infected with bloodborne pathogens. In August 1987, CDC published a document entitled "Recommendations for Prevention of HIV Transmission in Health-Care Settings" (1). In contrast to the 1983 document, the 1987 document recommended that blood and body fluid precautions be consistently used for all patients regardless of their bloodborne infection status. This extension of blood and body fluid precautions to all patients is referred to as "Universal Blood and Body Fluid Precautions" or "Universal Precautions." Under universal precautions, blood and certain body fluids of all patients are considered potentially infectious for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens.

*The August 1987 publication should be consulted for general information and specific recommendations not addressed in this update.

Update: HIV — Continued

Universal precautions are intended to prevent parenteral, mucous membrane, and nonintact skin exposures of health-care workers to bloodborne pathogens. In addition, immunization with HBV vaccine is recommended as an important adjunct to universal precautions for health-care workers who have exposures to blood (3,4).

Since the recommendations for universal precautions were published in August 1987, CDC and the Food and Drug Administration (FDA) have received requests for clarification of the following issues: 1) body fluids to which universal precautions apply, 2) use of protective barriers, 3) use of gloves for phlebotomy, 4) selection of gloves for use while observing universal precautions, and 5) need for making changes in waste management programs as a result of adopting universal precautions.

Body Fluids to Which Universal Precautions Apply

Universal precautions apply to blood and to other body fluids containing visible blood. Occupational transmission of HIV and HBV to health-care workers by blood is documented (4,5). **Blood is the single most important source of HIV, HBV, and other bloodborne pathogens in the occupational setting. Infection control efforts for HIV, HBV, and other bloodborne pathogens must focus on preventing exposures to blood as well as on delivery of HBV immunization.**

Universal precautions also apply to semen and vaginal secretions. Although both of these fluids have been implicated in the sexual transmission of HIV and HBV, they have not been implicated in occupational transmission from patient to health-care worker. This observation is not unexpected, since exposure to semen in the usual health-care setting is limited, and the routine practice of wearing gloves for performing vaginal examinations protects health-care workers from exposure to potentially infectious vaginal secretions.

Universal precautions also apply to tissues and to the following fluids: cerebrospinal fluid (CSF), synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. The risk of transmission of HIV and HBV from these fluids is unknown; epidemiologic studies in the health-care and community setting are currently inadequate to assess the potential risk to health-care workers from occupational exposures to them. However, HIV has been isolated from CSF, synovial, and amniotic fluid (6-8), and HBsAg has been detected in synovial fluid, amniotic fluid, and peritoneal fluid (9-11). One case of HIV transmission was reported after a percutaneous exposure to bloody pleural fluid obtained by needle aspiration (12). Whereas aseptic procedures used to obtain these fluids for diagnostic or therapeutic purposes protect health-care workers from skin exposures, they cannot prevent penetrating injuries due to contaminated needles or other sharp instruments.

Body Fluids to Which Universal Precautions Do Not Apply

Universal precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine, and vomitus unless they contain visible blood. The risk of transmission of HIV and HBV from these fluids and materials is extremely low or nonexistent. HIV has been isolated and HBsAg has been demonstrated in some of these fluids; however, epidemiologic studies in the health-care and community setting have not implicated these fluids or materials in the transmission of HIV and HBV infections (13,14). Some of the above fluids and excretions represent a potential source for nosocomial and community-acquired infections with other pathogens, and recommendations for preventing the transmission of nonbloodborne pathogens have been published (2).

*Update: HIV – Continued***Precautions for Other Body Fluids in Special Settings**

Human breast milk has been implicated in perinatal transmission of HIV, and HBsAg has been found in the milk of mothers infected with HBV (10,13). However, occupational exposure to human breast milk has not been implicated in the transmission of HIV nor HBV infection to health-care workers. Moreover, the health-care worker will not have the same type of intensive exposure to breast milk as the nursing neonate. Whereas universal precautions do not apply to human breast milk, gloves may be worn by health-care workers in situations where exposures to breast milk might be frequent, for example, in breast milk banking.

Saliva of some persons infected with HBV has been shown to contain HBV-DNA at concentrations 1/1,000 to 1/10,000 of that found in the infected person's serum (15). HBsAg-positive saliva has been shown to be infectious when injected into experimental animals and in human bite exposures (16–18). However, HBsAg-positive saliva has not been shown to be infectious when applied to oral mucous membranes in experimental primate studies (18) or through contamination of musical instruments or cardiopulmonary resuscitation dummies used by HBV carriers (19,20). Epidemiologic studies of nonsexual household contacts of HIV-infected patients, including several small series in which HIV transmission failed to occur after bites or after percutaneous inoculation or contamination of cuts and open wounds with saliva from HIV-infected patients, suggest that the potential for salivary transmission of HIV is remote (5,13,14,21,22). One case report from Germany has suggested the possibility of transmission of HIV in a household setting from an infected child to a sibling through a human bite (23). The bite did not break the skin or result in bleeding. Since the date of seroconversion to HIV was not known for either child in this case, evidence for the role of saliva in the transmission of virus is unclear (23). Another case report suggested the possibility of transmission of HIV from husband to wife by contact with saliva during kissing (24). However, follow-up studies did not confirm HIV infection in the wife (21).

Universal precautions do not apply to saliva. General infection control practices already in existence – including the use of gloves for digital examination of mucous membranes and endotracheal suctioning, and handwashing after exposure to saliva – should further minimize the minute risk, if any, for salivary transmission of HIV and HBV (1,25). Gloves need not be worn when feeding patients and when wiping saliva from skin.

Special precautions, however, are recommended for dentistry (1). Occupationally acquired infection with HBV in dental workers has been documented (4), and two possible cases of occupationally acquired HIV infection involving dentists have been reported (5,26). During dental procedures, contamination of saliva with blood is predictable, trauma to health-care workers' hands is common, and blood spattering may occur. Infection control precautions for dentistry minimize the potential for nonintact skin and mucous membrane contact of dental health-care workers to blood-contaminated saliva of patients. In addition, the use of gloves for oral examinations and treatment in the dental setting may also protect the patient's oral mucous membranes from exposures to blood, which may occur from breaks in the skin of dental workers' hands.

Use of Protective Barriers

Protective barriers reduce the risk of exposure of the health-care worker's skin or mucous membranes to potentially infective materials. For universal precautions,

Update: HIV – Continued

protective barriers reduce the risk of exposure to blood, body fluids containing visible blood, and other fluids to which universal precautions apply. Examples of protective barriers include gloves, gowns, masks, and protective eyewear. Gloves should reduce the incidence of contamination of hands, but they cannot prevent penetrating injuries due to needles or other sharp instruments. Masks and protective eyewear or face shields should reduce the incidence of contamination of mucous membranes of the mouth, nose, and eyes.

Universal precautions are intended to supplement rather than replace recommendations for routine infection control, such as handwashing and using gloves to prevent gross microbial contamination of hands (27). Because specifying the types of barriers needed for every possible clinical situation is impractical, some judgment must be exercised.

The risk of nosocomial transmission of HIV, HBV, and other bloodborne pathogens can be minimized if health-care workers use the following general guidelines:[†]

1. Take care to prevent injuries when using needles, scalpels, and other sharp instruments or devices; when handling sharp instruments after procedures; when cleaning used instruments; and when disposing of used needles. Do not recap used needles by hand; do not remove used needles from disposable syringes by hand; and do not bend, break, or otherwise manipulate used needles by hand. Place used disposable syringes and needles, scalpel blades, and other sharp items in puncture-resistant containers for disposal. Locate the puncture-resistant containers as close to the use area as is practical.
2. Use protective barriers to prevent exposure to blood, body fluids containing visible blood, and other fluids to which universal precautions apply. The type of protective barrier(s) should be appropriate for the procedure being performed and the type of exposure anticipated.
3. Immediately and thoroughly wash hands and other skin surfaces that are contaminated with blood, body fluids containing visible blood, or other body fluids to which universal precautions apply.

Glove Use for Phlebotomy

Gloves should reduce the incidence of blood contamination of hands during phlebotomy (drawing blood samples), but they cannot prevent penetrating injuries caused by needles or other sharp instruments. The likelihood of hand contamination with blood containing HIV, HBV, or other bloodborne pathogens during phlebotomy depends on several factors: 1) the skill and technique of the health-care worker, 2) the frequency with which the health-care worker performs the procedure (other factors being equal, the cumulative risk of blood exposure is higher for a health-care worker who performs more procedures), 3) whether the procedure occurs in a routine or emergency situation (where blood contact may be more likely), and 4) the prevalence of infection with bloodborne pathogens in the patient population. The likelihood of infection after skin exposure to blood containing HIV or HBV will depend on the concentration of virus (viral concentration is much higher for hepatitis B than for HIV), the duration of contact, the presence of skin lesions on the hands of the health-care worker, and – for HBV – the immune status of the health-care worker. Although not accurately quantified, the risk of HIV infection following intact skin contact with infective blood is certainly much less than the 0.5% risk following percutaneous

[†]The August 1987 publication should be consulted for general information and specific recommendations not addressed in this update.

Update: HIV – Continued

needlestick exposures (5). In universal precautions, *all* blood is assumed to be potentially infective for bloodborne pathogens, but in certain settings (e.g., volunteer blood-donation centers) the prevalence of infection with some bloodborne pathogens (e.g., HIV, HBV) is known to be very low. Some institutions have relaxed recommendations for using gloves for phlebotomy procedures by skilled phlebotomists in settings where the prevalence of bloodborne pathogens is known to be very low.

Institutions that judge that routine gloving for *all* phlebotomies is not necessary should periodically reevaluate their policy. Gloves should always be available to health-care workers who wish to use them for phlebotomy. In addition, the following general guidelines apply:

1. Use gloves for performing phlebotomy when the health-care worker has cuts, scratches, or other breaks in his/her skin.
2. Use gloves in situations where the health-care worker judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative patient.
3. Use gloves for performing finger and/or heel sticks on infants and children.
4. Use gloves when persons are receiving training in phlebotomy.

Selection of Gloves

The Center for Devices and Radiological Health, FDA, has responsibility for regulating the medical glove industry. Medical gloves include those marketed as sterile surgical or nonsterile examination gloves made of vinyl or latex. General purpose utility ("rubber") gloves are also used in the health-care setting, but they are not regulated by FDA since they are not promoted for medical use. There are no reported differences in barrier effectiveness between intact latex and intact vinyl used to manufacture gloves. Thus, the type of gloves selected should be appropriate for the task being performed.

The following general guidelines are recommended:

1. Use sterile gloves for procedures involving contact with normally sterile areas of the body.
2. Use examination gloves for procedures involving contact with mucous membranes, unless otherwise indicated, and for other patient care or diagnostic procedures that do not require the use of sterile gloves.
3. Change gloves between patient contacts.
4. Do not wash or disinfect surgical or examination gloves for reuse. Washing with surfactants may cause "wicking," i.e., the enhanced penetration of liquids through undetected holes in the glove. Disinfecting agents may cause deterioration.
5. Use general-purpose utility gloves (e.g., rubber household gloves) for housekeeping chores involving potential blood contact and for instrument cleaning and decontamination procedures. Utility gloves may be decontaminated and reused but should be discarded if they are peeling, cracked, or discolored, or if they have punctures, tears, or other evidence of deterioration.

Waste Management

Universal precautions are not intended to change waste management programs previously recommended by CDC for health-care settings (1). Policies for defining, collecting, storing, decontaminating, and disposing of infective waste are generally determined by institutions in accordance with state and local regulations. Information

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regarding waste management regulations in health-care settings may be obtained from state or local health departments or agencies responsible for waste management.

Reported by: Center for Devices and Radiological Health, Food and Drug Administration, Hospital Infections Program, AIDS Program, and Hepatitis Br, Div of Viral Diseases, Center for Infectious Diseases, National Institute for Occupational Safety and Health, CDC.

Editorial Note: Implementation of universal precautions does not eliminate the need for other category- or disease-specific isolation precautions, such as enteric precautions for infectious diarrhea or isolation for pulmonary tuberculosis (1,2). In addition to universal precautions, detailed precautions have been developed for the following procedures and/or settings in which prolonged or intensive exposures to blood occur: invasive procedures, dentistry, autopsies or morticians' services, dialysis, and the clinical laboratory. These detailed precautions are found in the August 21, 1987, "Recommendations for Prevention of HIV Transmission in Health-Care Settings" (1). In addition, specific precautions have been developed for research laboratories (28).

(Continued on page 387)

TABLE I. Summary - cases of specified notifiable diseases, United States

Disease	24th Week Ending			Cumulative, 24th Week Ending		
	Jun. 18, 1988	Jun. 20, 1987	Median 1983-1987	Jun. 18, 1988	Jun. 20, 1987	Median 1983-1987
Acquired Immunodeficiency Syndrome (AIDS)	198	U *	187	13,918	8,486	3,287
Aseptic meningitis	98	164	123	1,855	2,374	2,102
Encephalitis: Primary (arthropod-borne & unspec)	10	18	17	300	405	405
Post-infectious	1	4	3	44	54	54
Gonorrhea: Civilian	11,071	14,550	17,073	303,455	363,500	383,650
Military	189	282	407	5,531	7,687	9,454
Hepatitis: Type A	419	481	439	10,868	11,471	10,071
Type B	351	479	532	9,614	11,666	11,451
Non A, Non B	51	60	74	1,137	1,461	1,623
Unspecified	23	75	102	930	1,477	2,212
Legionellosis	18	16	16	378	399	314
Leprosy	6	1	3	80	93	121
Malaria	13	17	20	304	341	349
Measles: Total ¹	21	92	92	1,406	2,379	1,620
Indigenous	12	73	73	1,263	2,089	1,436
Imported	9	19	10	143	290	195
Meningococcal infections	44	55	55	1,592	1,648	1,575
Mumps	84	255	93	2,749	9,053	2,000
Pertussis	43	42	58	984	800	865
Rubella (German measles)	15	15	28	115	196	302
Syphilis (Primary & Secondary): Civilian	728	719	566	17,246	15,492	12,784
Military	1	2	2	84	80	93
Toxic Shock syndrome	6	5	5	131	145	178
Tuberculosis	435	442	475	8,999	9,396	9,397
Tularemia	7	9	8	68	64	68
Typhoid Fever	6	6	5	159	136	136
Typhus fever, tick-borne (RMSF)	27	35	35	130	154	177
Rabies, animal	78	85	111	1,874	2,368	2,368

TABLE II. Notifiable diseases of low frequency, United States

	Cum. 1988		Cum. 1988
Anthrax	-	Leptospirosis	13
Botulism: Foodborne (Md. 1)	10	Plague	2
Infant	16	Poliomyelitis, Paralytic	-
Other	2	Psittacosis (Upstate N.Y. 1)	36
Brucellosis (Minn. 1)	26	Rabies, human	-
Cholera	-	Tetanus	20
Congenital rubella syndrome	3	Trichinosis (Alaska 28)	37
Congenital syphilis, ages < 1 year	-		
Diphtheria	-		

*Because AIDS cases are not received weekly from all reporting areas, comparison of weekly figures may be misleading.

¹Nine of the 21 reported cases for this week were imported from a foreign country or can be directly traceable to a known internationally imported case within two generations.

Update: HIV – Continued

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Appendix B

Recommendations for Prevention of HIV Transmission in Health-Care Settings

Introduction

Human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS), is transmitted through sexual contact and exposure to infected blood or blood components and perinatally from mother to neonate. HIV has been isolated from blood, semen, vaginal secretions, saliva, tears, breast milk, cerebrospinal fluid, amniotic fluid, and urine and is likely to be isolated from other body fluids, secretions, and excretions. However, epidemiologic evidence has implicated only blood, semen, vaginal secretions, and possibly breast milk in transmission.

The increasing prevalence of HIV increases the risk that health-care workers will be exposed to blood from patients infected with HIV, especially when blood and body-fluid precautions are not followed for all patients. Thus, this document emphasizes the need for health-care workers to consider all patients as potentially infected with HIV and/or other blood-borne pathogens and to adhere rigorously to infection-control precautions for minimizing the risk of exposure to blood and body fluids of all patients.

The recommendations contained in this document consolidate and update CDC recommendations published earlier for preventing HIV transmission in health-care settings: precautions for clinical and laboratory staffs (1) and precautions for health-care workers and allied professionals (2); recommendations for preventing HIV transmission in the workplace (3) and during invasive procedures (4); recommendations for preventing possible transmission of HIV from tears (5); and recommendations for providing dialysis treatment for HIV-infected patients (6). These recommendations also update portions of the "Guideline for Isolation Precautions in Hospitals" (7) and reemphasize some of the recommendations contained in "Infection Control Practices for Dentistry" (8). The recommendations contained in this document have been developed for use in health-care settings and emphasize the need to treat blood and other body fluids from all patients as potentially infective. These same prudent precautions also should be taken in other settings in which persons may be exposed to blood or other body fluids.

Definition of Health-Care Workers

Health-care workers are defined as persons, including students and trainees, whose activities involve contact with patients or with blood or other body fluids from patients in a health-care setting.

Health-Care Workers with AIDS

As of July 10, 1987, a total of 1,875 (5.8%) of 32,395 adults with AIDS, who had been reported to the CDC national surveillance system and for whom occupational information was available, reported being employed in a health-care or clinical laboratory setting. In comparison, 6.8 million persons—representing 5.6% of the U.S. labor force—were employed in health services. Of the health-care workers with AIDS, 95% have been reported to exhibit high-risk behavior; for the remaining 5%, the means of HIV acquisition was undetermined. Health-care workers with AIDS were significantly more likely than other workers to have an undetermined risk (5% versus 3%, respectively). For both health-care workers and non-health-care workers with AIDS, the proportion with an undetermined risk has not increased since 1982.

AIDS patients initially reported as not belonging to recognized risk groups are investigated by state and local health departments to determine whether possible risk factors exist. Of all health-care workers with AIDS reported to CDC who were initially characterized as not having an identified risk and for whom follow-up information was available, 66% have been reclassified because risk factors were identified or because the patient was found not to meet the surveillance case definition for AIDS. Of the 87 health-care workers currently categorized as having no identifiable risk, information is incomplete on 16 (18%) because of death or refusal to be interviewed; 38 (44%) are still being investigated. The remaining 33 (38%) health-care workers were interviewed or had other follow-up information available. The occupations of these 33 were as follows: five physicians (15%), three of whom were surgeons; one dentist (3%); three nurses (9%); nine nursing assistants (27%); seven housekeeping or maintenance workers (21%); three clinical laboratory technicians (9%); one therapist (3%); and four others who did not have contact with patients (12%). Although 15 of these 33 health-care workers reported parenteral and/or other non-needlestick exposure to blood or body fluids from patients in the 10 years preceding their diagnosis of AIDS, none of these exposures involved a patient with AIDS or known HIV infection.

Risk to Health-Care Workers of Acquiring HIV in Health-Care Settings

Health-care workers with documented percutaneous or mucous-membrane exposures to blood or body fluids of HIV-infected patients have been prospectively evaluated to determine the risk of infection after such exposures. As of June 30, 1987, 883 health-care workers have been tested for antibody to HIV in an ongoing surveillance project conducted by CDC (9). Of these, 708 (80%) had percutaneous exposures to blood, and 175 (20%) had a mucous membrane or an open wound contaminated by blood or body fluid. Of 396 health-care workers, each of whom had only a convalescent-phase serum sample obtained and tested ≥ 90 days post-exposure, one—for whom heterosexual transmission could not be ruled out—was seropositive for HIV antibody. For 425 additional health-care workers, both acute- and convalescent-phase serum samples were obtained and tested; none of 74 health-care workers with nonpercutaneous exposures seroconverted, and three (0.9%) of 351

with percutaneous exposures seroconverted. None of these three health-care workers had other documented risk factors for infection.

Two other prospective studies to assess the risk of nosocomial acquisition of HIV infection for health-care workers are ongoing in the United States. As of April 30, 1987, 332 health-care workers with a total of 453 needlestick or mucous-membrane exposures to the blood or other body fluids of HIV-infected patients were tested for HIV antibody at the National Institutes of Health (10). These exposed workers included 103 with needlestick injuries and 229 with mucous-membrane exposures; none had seroconverted. A similar study at the University of California of 129 health-care workers with documented needlestick injuries or mucous-membrane exposures to blood or other body fluids from patients with HIV infection has not identified any seroconversions (11). Results of a prospective study in the United Kingdom identified no evidence of transmission among 150 health-care workers with parenteral or mucous-membrane exposures to blood or other body fluids, secretions, or excretions from patients with HIV infection (12).

In addition to health-care workers enrolled in prospective studies, eight persons who provided care to infected patients and denied other risk factors have been reported to have acquired HIV infection. Three of these health-care workers had needlestick exposures to blood from infected patients (13-15). Two were persons who provided nursing care to infected persons; although neither sustained a needlestick, both had extensive contact with blood or other body fluids, and neither observed recommended barrier precautions (16,17). The other three were health-care workers with non-needlestick exposures to blood from infected patients (18). Although the exact route of transmission for these last three infections is not known, all three persons had direct contact of their skin with blood from infected patients, all had skin lesions that may have been contaminated by blood, and one also had a mucous-membrane exposure.

A total of 1,231 dentists and hygienists, many of whom practiced in areas with many AIDS cases, participated in a study to determine the prevalence of antibody to HIV; one dentist (0.1%) had HIV antibody. Although no exposure to a known HIV-infected person could be documented, epidemiologic investigation did not identify any other risk factor for infection. The infected dentist, who also had a history of sustaining needlestick injuries and trauma to his hands, did not routinely wear gloves when providing dental care (19).

Precautions To Prevent Transmission of HIV

Universal Precautions

Since medical history and examination cannot reliably identify all patients infected with HIV or other blood-borne pathogens, blood and body-fluid precautions should be consistently used for all patients. This approach, previously recommended by CDC (3,4), and referred to as "universal blood and body-fluid precautions" or "universal precautions," should be used in the care of all patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown (20).

1. All health-care workers should routinely use appropriate barrier precautions to prevent skin and mucous-membrane exposure when contact with blood or other body fluids of any patient is anticipated. Gloves should be worn for touching blood and body fluids, mucous membranes, or non-intact skin of all patients, for handling items or surfaces soiled with blood or body fluids, and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Masks and protective eyewear or face shields should be worn during procedures that are likely to generate droplets of blood or other body fluids to prevent exposure of mucous membranes of the mouth, nose, and eyes. Gowns or aprons should be worn during procedures that are likely to generate splashes of blood or other body fluids.
2. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other body fluids. Hands should be washed immediately after gloves are removed.
3. All health-care workers should take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments after procedures. To prevent needlestick injuries, needles should not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are used, disposable syringes and needles, scalpel blades, and other sharp items should be placed in puncture-resistant containers for disposal; the puncture-resistant containers should be located as close as practical to the use area. Large-bore reusable needles should be placed in a puncture-resistant container for transport to the reprocessing area.
4. Although saliva has not been implicated in HIV transmission, to minimize the need for emergency mouth-to-mouth resuscitation, mouthpieces, resuscitation bags, or other ventilation devices should be available for use in areas in which the need for resuscitation is predictable.
5. Health-care workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.
6. Pregnant health-care workers are not known to be at greater risk of contracting HIV infection than health-care workers who are not pregnant; however, if a health-care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health-care workers should be especially familiar with and strictly adhere to precautions to minimize the risk of HIV transmission.

Implementation of universal blood and body-fluid precautions for all patients eliminates the need for use of the isolation category of "Blood and Body Fluid Precautions" previously recommended by CDC (7) for patients known or suspected to be infected with blood-borne pathogens. Isolation precautions (e.g., enteric, "AFB" [7]) should be used as necessary if associated conditions, such as infectious diarrhea or tuberculosis, are diagnosed or suspected.

Precautions for Invasive Procedures

In this document, an invasive procedure is defined as surgical entry into tissues, cavities, or organs or repair of major traumatic injuries 1) in an operating or delivery

room, emergency department, or outpatient setting, including both physicians' and dentists' offices; 2) cardiac catheterization and angiographic procedures; 3) a vaginal or cesarean delivery or other invasive obstetric procedure during which bleeding may occur; or 4) the manipulation, cutting, or removal of any oral or perioral tissues, including tooth structure, during which bleeding occurs or the potential for bleeding exists. The universal blood and body-fluid precautions listed above, combined with the precautions listed below, should be the minimum precautions for all such invasive procedures.

1. All health-care workers who participate in invasive procedures must routinely use appropriate barrier precautions to prevent skin and mucous-membrane contact with blood and other body fluids of all patients. Gloves and surgical masks must be worn for all invasive procedures. Protective eyewear or face shields should be worn for procedures that commonly result in the generation of droplets, splashing of blood or other body fluids, or the generation of bone chips. Gowns or aprons made of materials that provide an effective barrier should be worn during invasive procedures that are likely to result in the splashing of blood or other body fluids. All health-care workers who perform or assist in vaginal or cesarean deliveries should wear gloves and gowns when handling the placenta or the infant until blood and amniotic fluid have been removed from the infant's skin and should wear gloves during post-delivery care of the umbilical cord.
2. If a glove is torn or a needlestick or other injury occurs, the glove should be removed and a new glove used as promptly as patient safety permits; the needle or instrument involved in the incident should also be removed from the sterile field.

Precautions for Dentistry*

Blood, saliva, and gingival fluid from all dental patients should be considered infective. Special emphasis should be placed on the following precautions for preventing transmission of blood-borne pathogens in dental practice in both institutional and non-institutional settings.

1. In addition to wearing gloves for contact with oral mucous membranes of all patients, all dental workers should wear surgical masks and protective eyewear or chin-length plastic face shields during dental procedures in which splashing or spattering of blood, saliva, or gingival fluids is likely. Rubber dams, high-speed evacuation, and proper patient positioning, when appropriate, should be utilized to minimize generation of droplets and spatter.
2. Handpieces should be sterilized after use with each patient, since blood, saliva, or gingival fluid of patients may be aspirated into the handpiece or waterline. Handpieces that cannot be sterilized should at least be flushed, the outside surface cleaned and wiped with a suitable chemical germicide, and then rinsed. Handpieces should be flushed at the beginning of the day and after use with each patient. Manufacturers' recommendations should be followed for use and maintenance of waterlines and check valves and for flushing of handpieces. The same precautions should be used for ultrasonic scalers and air/water syringes.

*General infection-control precautions are more specifically addressed in previous recommendations for infection-control practices for dentistry (8).

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3. Blood and saliva should be thoroughly and carefully cleaned from material that has been used in the mouth (e.g., impression materials, bite registration), especially before polishing and grinding intra-oral devices. Contaminated materials, impressions, and intra-oral devices should also be cleaned and disinfected before being handled in the dental laboratory and before they are placed in the patient's mouth. Because of the increasing variety of dental materials used intra-orally, dental workers should consult with manufacturers as to the stability of specific materials when using disinfection procedures.
4. Dental equipment and surfaces that are difficult to disinfect (e.g., light handles or X-ray-unit heads) and that may become contaminated should be wrapped with impervious-backed paper, aluminum foil, or clear plastic wrap. The coverings should be removed and discarded, and clean coverings should be put in place after use with each patient.

Precautions for Autopsies or Morticians' Services

In addition to the universal blood and body-fluid precautions listed above, the following precautions should be used by persons performing postmortem procedures:

1. All persons performing or assisting in postmortem procedures should wear gloves, masks, protective eyewear, gowns, and waterproof aprons.
2. Instruments and surfaces contaminated during postmortem procedures should be decontaminated with an appropriate chemical germicide.

Precautions for Dialysis

Patients with end-stage renal disease who are undergoing maintenance dialysis and who have HIV infection can be dialyzed in hospital-based or free-standing dialysis units using conventional infection-control precautions (21). Universal blood and body-fluid precautions should be used when dialyzing all patients.

Strategies for disinfecting the dialysis fluid pathways of the hemodialysis machine are targeted to control bacterial contamination and generally consist of using 500-750 parts per million (ppm) of sodium hypochlorite (household bleach) for 30-40 minutes or 1.5%-2.0% formaldehyde overnight. In addition, several chemical germicides formulated to disinfect dialysis machines are commercially available. None of these protocols or procedures need to be changed for dialyzing patients infected with HIV.

Patients infected with HIV can be dialyzed by either hemodialysis or peritoneal dialysis and do not need to be isolated from other patients. The type of dialysis treatment (i.e., hemodialysis or peritoneal dialysis) should be based on the needs of the patient. The dialyzer may be discarded after each use. Alternatively, centers that reuse dialyzers—i.e., a specific single-use dialyzer is issued to a specific patient, removed, cleaned, disinfected, and reused several times on the same patient only—may include HIV-infected patients in the dialyzer-reuse program. An individual dialyzer must never be used on more than one patient.

Precautions for Laboratories[†]

Blood and other body fluids from all patients should be considered infective. To supplement the universal blood and body-fluid precautions listed above, the following precautions are recommended for health-care workers in clinical laboratories.

[†]Additional precautions for research and industrial laboratories are addressed elsewhere (22,23).

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1. All specimens of blood and body fluids should be put in a well-constructed container with a secure lid to prevent leaking during transport. Care should be taken when collecting each specimen to avoid contaminating the outside of the container and of the laboratory form accompanying the specimen.
2. All persons processing blood and body-fluid specimens (e.g., removing tops from vacuum tubes) should wear gloves. Masks and protective eyewear should be worn if mucous-membrane contact with blood or body fluids is anticipated. Gloves should be changed and hands washed after completion of specimen processing.
3. For routine procedures, such as histologic and pathologic studies or microbiologic culturing, a biological safety cabinet is not necessary. However, biological safety cabinets (Class I or II) should be used whenever procedures are conducted that have a high potential for generating droplets. These include activities such as blending, sonicating, and vigorous mixing.
4. Mechanical pipetting devices should be used for manipulating all liquids in the laboratory. Mouth pipetting must not be done.
5. Use of needles and syringes should be limited to situations in which there is no alternative, and the recommendations for preventing injuries with needles outlined under universal precautions should be followed.
6. Laboratory work surfaces should be decontaminated with an appropriate chemical germicide after a spill of blood or other body fluids and when work activities are completed.
7. Contaminated materials used in laboratory tests should be decontaminated before reprocessing or be placed in bags and disposed of in accordance with institutional policies for disposal of infective waste (24).
8. Scientific equipment that has been contaminated with blood or other body fluids should be decontaminated and cleaned before being repaired in the laboratory or transported to the manufacturer.
9. All persons should wash their hands after completing laboratory activities and should remove protective clothing before leaving the laboratory.

Implementation of universal blood and body-fluid precautions for all patients eliminates the need for warning labels on specimens since blood and other body fluids from all patients should be considered infective.

Environmental Considerations for HIV Transmission

No environmentally mediated mode of HIV transmission has been documented. Nevertheless, the precautions described below should be taken routinely in the care of all patients.

Sterilization and Disinfection

Standard sterilization and disinfection procedures for patient-care equipment currently recommended for use (25,26) in a variety of health-care settings—including hospitals, medical and dental clinics and offices, hemodialysis centers, emergency-care facilities, and long-term nursing-care facilities—are adequate to sterilize or disinfect instruments, devices, or other items contaminated with blood or other body fluids from persons infected with blood-borne pathogens including HIV (21,23).

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Instruments or devices that enter sterile tissue or the vascular system of any patient or through which blood flows should be sterilized before reuse. Devices or items that contact intact mucous membranes should be sterilized or receive high-level disinfection, a procedure that kills vegetative organisms and viruses but not necessarily large numbers of bacterial spores. Chemical germicides that are registered with the U.S. Environmental Protection Agency (EPA) as "sterilants" may be used either for sterilization or for high-level disinfection depending on contact time.

Contact lenses used in trial fittings should be disinfected after each fitting by using a hydrogen peroxide contact lens disinfecting system or, if compatible, with heat (78 C-80 C [172.4 F-176.0 F]) for 10 minutes.

Medical devices or instruments that require sterilization or disinfection should be thoroughly cleaned before being exposed to the germicide, and the manufacturer's instructions for the use of the germicide should be followed. Further, it is important that the manufacturer's specifications for compatibility of the medical device with chemical germicides be closely followed. Information on specific label claims of commercial germicides can be obtained by writing to the Disinfectants Branch, Office of Pesticides, Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

Studies have shown that HIV is inactivated rapidly after being exposed to commonly used chemical germicides at concentrations that are much lower than used in practice (27-30). Embalming fluids are similar to the types of chemical germicides that have been tested and found to completely inactivate HIV. In addition to commercially available chemical germicides, a solution of sodium hypochlorite (household bleach) prepared daily is an inexpensive and effective germicide. Concentrations ranging from approximately 500 ppm (1:100 dilution of household bleach) sodium hypochlorite to 5,000 ppm (1:10 dilution of household bleach) are effective depending on the amount of organic material (e.g., blood, mucus) present on the surface to be cleaned and disinfected. Commercially available chemical germicides may be more compatible with certain medical devices that might be corroded by repeated exposure to sodium hypochlorite, especially to the 1:10 dilution.

Survival of HIV in the Environment

The most extensive study on the survival of HIV after drying involved greatly concentrated HIV samples, i.e., 10 million tissue-culture infectious doses per milliliter (31). This concentration is at least 100,000 times greater than that typically found in the blood or serum of patients with HIV infection. HIV was detectable by tissue-culture techniques 1-3 days after drying, but the rate of inactivation was rapid. Studies performed at CDC have also shown that drying HIV causes a rapid (within several hours) 1-2 log (90%-99%) reduction in HIV concentration. In tissue-culture fluid, cell-free HIV could be detected up to 15 days at room temperature, up to 11 days at 37 C (98.6 F), and up to 1 day if the HIV was cell-associated.

When considered in the context of environmental conditions in health-care facilities, these results do not require any changes in currently recommended sterilization, disinfection, or housekeeping strategies. When medical devices are contaminated with blood or other body fluids, existing recommendations include the cleaning of these instruments, followed by disinfection or sterilization, depending on the type of medical device. These protocols assume "worst-case" conditions of

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extreme virologic and microbiologic contamination, and whether viruses have been inactivated after drying plays no role in formulating these strategies. Consequently, no changes in published procedures for cleaning, disinfecting, or sterilizing need to be made.

Housekeeping

Environmental surfaces such as walls, floors, and other surfaces are not associated with transmission of infections to patients or health-care workers. Therefore, extraordinary attempts to disinfect or sterilize these environmental surfaces are not necessary. However, cleaning and removal of soil should be done routinely.

Cleaning schedules and methods vary according to the area of the hospital or institution, type of surface to be cleaned, and the amount and type of soil present. Horizontal surfaces (e.g., bedside tables and hard-surfaced flooring) in patient-care areas are usually cleaned on a regular basis, when soiling or spills occur, and when a patient is discharged. Cleaning of walls, blinds, and curtains is recommended only if they are visibly soiled. Disinfectant fogging is an unsatisfactory method of decontaminating air and surfaces and is not recommended.

Disinfectant-detergent formulations registered by EPA can be used for cleaning environmental surfaces, but the actual physical removal of microorganisms by scrubbing is probably at least as important as any antimicrobial effect of the cleaning agent used. Therefore, cost, safety, and acceptability by housekeepers can be the main criteria for selecting any such registered agent. The manufacturers' instructions for appropriate use should be followed.

Cleaning and Decontaminating Spills of Blood or Other Body Fluids

Chemical germicides that are approved for use as "hospital disinfectants" and are tuberculocidal when used at recommended dilutions can be used to decontaminate spills of blood and other body fluids. Strategies for decontaminating spills of blood and other body fluids in a patient-care setting are different than for spills of cultures or other materials in clinical, public health, or research laboratories. In patient-care areas, visible material should first be removed and then the area should be decontaminated. With large spills of cultured or concentrated infectious agents in the laboratory, the contaminated area should be flooded with a liquid germicide before cleaning, then decontaminated with fresh germicidal chemical. In both settings, gloves should be worn during the cleaning and decontaminating procedures.

Laundry

Although soiled linen has been identified as a source of large numbers of certain pathogenic microorganisms, the risk of actual disease transmission is negligible. Rather than rigid procedures and specifications, hygienic and common-sense storage and processing of clean and soiled linen are recommended (26). Soiled linen should be handled as little as possible and with minimum agitation to prevent gross microbial contamination of the air and of persons handling the linen. All soiled linen should be bagged at the location where it was used; it should not be sorted or rinsed in patient-care areas. Linen soiled with blood or body fluids should be placed and transported in bags that prevent leakage. If hot water is used, linen should be washed

with detergent in water at least 71 C (160 F) for 25 minutes. If low-temperature (≤ 70 C [158 F]) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration should be used.

Infective Waste

There is no epidemiologic evidence to suggest that most hospital waste is any more infective than residential waste. Moreover, there is no epidemiologic evidence that hospital waste has caused disease in the community as a result of improper disposal. Therefore, identifying wastes for which special precautions are indicated is largely a matter of judgment about the relative risk of disease transmission. The most practical approach to the management of infective waste is to identify those wastes with the potential for causing infection during handling and disposal and for which some special precautions appear prudent. Hospital wastes for which special precautions appear prudent include microbiology laboratory waste, pathology waste, and blood specimens or blood products. While any item that has had contact with blood, exudates, or secretions may be potentially infective, it is not usually considered practical or necessary to treat all such waste as infective (23,26). Infective waste, in general, should either be incinerated or should be autoclaved before disposal in a sanitary landfill. Bulk blood, suctioned fluids, excretions, and secretions may be carefully poured down a drain connected to a sanitary sewer. Sanitary sewers may also be used to dispose of other infectious wastes capable of being ground and flushed into the sewer.

Implementation of Recommended Precautions

Employers of health-care workers should ensure that policies exist for:

1. Initial orientation and continuing education and training of all health-care workers—including students and trainees—on the epidemiology, modes of transmission, and prevention of HIV and other blood-borne infections and the need for routine use of universal blood and body-fluid precautions for all patients.
2. Provision of equipment and supplies necessary to minimize the risk of infection with HIV and other blood-borne pathogens.
3. Monitoring adherence to recommended protective measures. When monitoring reveals a failure to follow recommended precautions, counseling, education, and/or re-training should be provided, and, if necessary, appropriate disciplinary action should be considered.

Professional associations and labor organizations, through continuing education efforts, should emphasize the need for health-care workers to follow recommended precautions.

Serologic Testing for HIV Infection

Background

A person is identified as infected with HIV when a sequence of tests, starting with repeated enzyme immunoassays (EIA) and including a Western blot or similar, more specific assay, are repeatedly reactive. Persons infected with HIV usually develop antibody against the virus within 6-12 weeks after infection.

The sensitivity of the currently licensed EIA tests is at least 99% when they are performed under optimal laboratory conditions on serum specimens from persons infected for ≥ 12 weeks. Optimal laboratory conditions include the use of reliable reagents, provision of continuing education of personnel, quality control of procedures, and participation in performance-evaluation programs. Given this performance, the probability of a false-negative test is remote except during the first several weeks after infection, before detectable antibody is present. The proportion of infected persons with a false-negative test attributed to absence of antibody in the early stages of infection is dependent on both the incidence and prevalence of HIV infection in a population (Table 1).

The specificity of the currently licensed EIA tests is approximately 99% when repeatedly reactive tests are considered. Repeat testing of initially reactive specimens by EIA is required to reduce the likelihood of laboratory error. To increase further the specificity of serologic tests, laboratories must use a supplemental test, most often the Western blot, to validate repeatedly reactive EIA results. Under optimal laboratory conditions, the sensitivity of the Western blot test is comparable to or greater than that of a repeatedly reactive EIA, and the Western blot is highly specific when strict criteria are used to interpret the test results. The testing sequence of a repeatedly reactive EIA and a positive Western blot test is highly predictive of HIV infection, even in a population with a low prevalence of infection (Table 2). If the Western blot test result is indeterminant, the testing sequence is considered equivocal for HIV infection.

TABLE 1. Estimated annual number of patients infected with HIV not detected by HIV-antibody testing in a hypothetical hospital with 10,000 admissions/year*

Beginning prevalence of HIV infection	Annual incidence of HIV infection	Approximate number of HIV-infected patients	Approximate number of HIV-infected patients not detected
5.0%	1.0%	550	17-18
5.0%	0.5%	525	11-12
1.0%	0.2%	110	3-4
1.0%	0.1%	105	2-3
0.1%	0.02%	11	0-1
0.1%	0.01%	11	0-1

*The estimates are based on the following assumptions: 1) the sensitivity of the screening test is 99% (i.e., 99% of HIV-infected persons with antibody will be detected); 2) persons infected with HIV will not develop detectable antibody (seroconvert) until 6 weeks (1.5 months) after infection; 3) new infections occur at an equal rate throughout the year; 4) calculations of the number of HIV-infected persons in the patient population are based on the mid-year prevalence, which is the beginning prevalence plus half the annual incidence of infections.

When this occurs, the Western blot test should be repeated on the same serum sample, and, if still indeterminant, the testing sequence should be repeated on a sample collected 3-6 months later. Use of other supplemental tests may aid in interpreting of results on samples that are persistently indeterminant by Western blot.

Testing of Patients

Previous CDC recommendations have emphasized the value of HIV serologic testing of patients for: 1) management of parenteral or mucous-membrane exposures of health-care workers, 2) patient diagnosis and management, and 3) counseling and serologic testing to prevent and control HIV transmission in the community. In addition, more recent recommendations have stated that hospitals, in conjunction with state and local health departments, should periodically determine the prevalence of HIV infection among patients from age groups at highest risk of infection (32).

Adherence to universal blood and body-fluid precautions recommended for the care of all patients will minimize the risk of transmission of HIV and other blood-borne pathogens from patients to health-care workers. The utility of routine HIV serologic testing of patients as an adjunct to universal precautions is unknown. Results of such testing may not be available in emergency or outpatient settings. In addition, some recently infected patients will not have detectable antibody to HIV (Table 1).

Personnel in some hospitals have advocated serologic testing of patients in settings in which exposure of health-care workers to large amounts of patients' blood may be anticipated. Specific patients for whom serologic testing has been advocated include those undergoing major operative procedures and those undergoing treatment in critical-care units, especially if they have conditions involving uncontrolled bleeding. Decisions regarding the need to establish testing programs for patients should be made by physicians or individual institutions. In addition, when deemed appropriate, testing of individual patients may be performed on agreement between the patient and the physician providing care.

In addition to the universal precautions recommended for all patients, certain additional precautions for the care of HIV-infected patients undergoing major surgical operations have been proposed by personnel in some hospitals. For example, surgical procedures on an HIV-infected patient might be altered so that hand-to-hand passing of sharp instruments would be eliminated; stapling instruments rather than

TABLE 2. Predictive value of positive HIV-antibody tests in hypothetical populations with different prevalences of infection

	Prevalence of infection	Predictive value of positive test*
Repeatedly reactive enzyme immunoassay (EIA)†	0.2%	28.41%
	2.0%	80.16%
	20.0%	98.02%
Repeatedly reactive EIA followed by positive Western blot (WB)‡	0.2%	99.75%
	2.0%	99.97%
	20.0%	99.99%

*Proportion of persons with positive test results who are actually infected with HIV.

†Assumes EIA sensitivity of 99.0% and specificity of 99.5%.

‡Assumes WB sensitivity of 99.0% and specificity of 99.9%.

hand-suturing equipment might be used to perform tissue approximation; electrocautery devices rather than scalpels might be used as cutting instruments; and, even though uncomfortable, gowns that totally prevent seepage of blood onto the skin of members of the operative team might be worn. While such modifications might further minimize the risk of HIV infection for members of the operative team, some of these techniques could result in prolongation of operative time and could potentially have an adverse effect on the patient.

Testing programs, if developed, should include the following principles:

- Obtaining consent for testing.
- Informing patients of test results, and providing counseling for seropositive patients by properly trained persons.
- Assuring that confidentiality safeguards are in place to limit knowledge of test results to those directly involved in the care of infected patients or as required by law.
- Assuring that identification of infected patients will not result in denial of needed care or provision of suboptimal care.
- Evaluating prospectively 1) the efficacy of the program in reducing the incidence of parenteral, mucous-membrane, or significant cutaneous exposures of health-care workers to the blood or other body fluids of HIV-infected patients and 2) the effect of modified procedures on patients.

Testing of Health-Care Workers

Although transmission of HIV from infected health-care workers to patients has not been reported, transmission during invasive procedures remains a possibility. Transmission of hepatitis B virus (HBV)—a blood-borne agent with a considerably greater potential for nosocomial spread—from health-care workers to patients has been documented. Such transmission has occurred in situations (e.g., oral and gynecologic surgery) in which health-care workers, when tested, had very high concentrations of HBV in their blood (at least 100 million infectious virus particles per milliliter, a concentration much higher than occurs with HIV infection), and the health-care workers sustained a puncture wound while performing invasive procedures or had exudative or weeping lesions or microlacerations that allowed virus to contaminate instruments or open wounds of patients (33,34).

The hepatitis B experience indicates that only those health-care workers who perform certain types of invasive procedures have transmitted HBV to patients. Adherence to recommendations in this document will minimize the risk of transmission of HIV and other blood-borne pathogens from health-care workers to patients during invasive procedures. Since transmission of HIV from infected health-care workers performing invasive procedures to their patients has not been reported and would be expected to occur only very rarely, if at all, the utility of routine testing of such health-care workers to prevent transmission of HIV cannot be assessed. If consideration is given to developing a serologic testing program for health-care workers who perform invasive procedures, the frequency of testing, as well as the issues of consent, confidentiality, and consequences of test results—as previously outlined for testing programs for patients—must be addressed.

Management of Infected Health-Care Workers

Health-care workers with impaired immune systems resulting from HIV infection or other causes are at increased risk of acquiring or experiencing serious complications of infectious disease. Of particular concern is the risk of severe infection following exposure to patients with infectious diseases that are easily transmitted if appropriate precautions are not taken (e.g., measles, varicella). Any health-care worker with an impaired immune system should be counseled about the potential risk associated with taking care of patients with any transmissible infection and should continue to follow existing recommendations for infection control to minimize risk of exposure to other infectious agents (7,35). Recommendations of the Immunization Practices Advisory Committee (ACIP) and institutional policies concerning requirements for vaccinating health-care workers with live-virus vaccines (e.g., measles, rubella) should also be considered.

The question of whether workers infected with HIV—especially those who perform invasive procedures—can adequately and safely be allowed to perform patient-care duties or whether their work assignments should be changed must be determined on an individual basis. These decisions should be made by the health-care worker's personal physician(s) in conjunction with the medical directors and personnel health service staff of the employing institution or hospital.

Management of Exposures

If a health-care worker has a parenteral (e.g., needlestick or cut) or mucous-membrane (e.g., splash to the eye or mouth) exposure to blood or other body fluids or has a cutaneous exposure involving large amounts of blood or prolonged contact with blood—especially when the exposed skin is chapped, abraded, or afflicted with dermatitis—the source patient should be informed of the incident and tested for serologic evidence of HIV infection after consent is obtained. Policies should be developed for testing source patients in situations in which consent cannot be obtained (e.g., an unconscious patient).

If the source patient has AIDS, is positive for HIV antibody, or refuses the test, the health-care worker should be counseled regarding the risk of infection and evaluated clinically and serologically for evidence of HIV infection as soon as possible after the exposure. The health-care worker should be advised to report and seek medical evaluation for any acute febrile illness that occurs within 12 weeks after the exposure. Such an illness—particularly one characterized by fever, rash, or lymphadenopathy—may be indicative of recent HIV infection. Seronegative health-care workers should be retested 6 weeks post-exposure and on a periodic basis thereafter (e.g., 12 weeks and 6 months after exposure) to determine whether transmission has occurred. During this follow-up period—especially the first 6-12 weeks after exposure, when most infected persons are expected to seroconvert—exposed health-care workers should follow U.S. Public Health Service (PHS) recommendations for preventing transmission of HIV (36,37).

No further follow-up of a health-care worker exposed to infection as described above is necessary if the source patient is seronegative unless the source patient is at high risk of HIV infection. In the latter case, a subsequent specimen (e.g., 12 weeks following exposure) may be obtained from the health-care worker for antibody

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testing. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized. Serologic testing should be available to all health-care workers who are concerned that they may have been infected with HIV.

If a patient has a parenteral or mucous-membrane exposure to blood or other body fluid of a health-care worker, the patient should be informed of the incident, and the same procedure outlined above for management of exposures should be followed for both the source health-care worker and the exposed patient.

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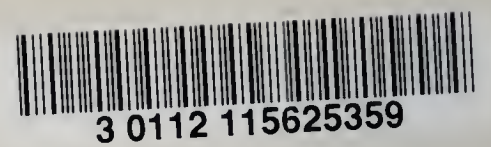
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APPENDIX C

Evaluation of Employer Training and Education Programs

Training programs must be evaluated through program review and discussion with management and employees.

1. Training programs shall normally include epidemiology, clinical presentation, modes of transmission and prevention of HBV and HIV as well as protective measures to be taken to prevent exposure.
2. The following questions provide a general outline of training topics to be reviewed when conducting an inspection at a health care facility. Responses shall be documented in the case file. Areas of interest include, but are not limited to, direct patient care areas, emergency room, operating rooms, clinical laboratories, x-ray, housekeeping and laundry.
 - a. Has a training and information program been established for employees actually or potentially exposed to blood and/or body fluids?
 - b. How often is training provided and does it cover:
 - (1) Universal precautions?
 - (2) Personal protective equipment?
 - (3) Workplace practices including blood drawing, room cleaning, laundry handling, cleanup of blood spills?
 - (4) Needlestick exposure/management?
 - (5) Hepatitis B Vaccination?
 - c. Does new employee orientation cover infectious disease control?
 - d. Does the employer evaluate the effectiveness of the training program through monitoring of employee compliance with the guidelines?



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- e. Have employees been informed of the precautionary measures outlined in the CDC guidelines?
- f. Is personal protective equipment provided to employees? In all appropriate locations? (Specifically, ask about gloves, masks, eye protection, gowns (as appropriate).)
- g. Is the necessary equipment (i.e., mouthpieces, resuscitation bags, or other ventilation devices) provided for administering mouth-to-mouth resuscitation on potentially infected patients?
- h. Does training identify the specific procedures implemented by the employer to provide protection, such as proper use of personal protective equipment?
- i. Are facilities available to comply with workplace practices, such as handwashing sinks, needle containers, detergents and disinfectants to clean up spills?
- j. Are employees aware of specific workplace practices to follow when appropriate? Specifically ask about:
 - o Handwashing.
 - o Handling sharp instruments.
 - o Routine examinations.
 - o Blood spills.
 - o Handling of laundry.
 - o Disposal of contaminated materials.
 - o Reusable equipment.
- k. Are workers aware of procedures to follow after a needlestick or blood exposure? Have they had such experiences, and are the guidelines followed?
- l. Are employees aware of the Hepatitis B vaccination program? Do they take advantage of it?